IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No._____
	)	
SANDOZ, INC.	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Wyeth, by its attorneys, for its complaint against Sandoz, Inc. ("Sandoz"), alleges as follows:

The Parties

1. Plaintiff Wyeth is a corporation organized and existing under the laws of Delaware and has its headquarters at 5 Giralda Farms, Madison, New Jersey 07940.

2. Upon information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of Colorado, has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, and does business in the State of Delaware.

3. Upon information and belief, Sandoz is in the business of manufacturing, distributing and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

Jurisdiction and Venue

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,500,814 ("the '814 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Sandoz based on Sandoz's continuous and systematic business contacts with the State of Delaware. Additionally, in a telephone conversation on May 23, 2008, counsel for Sandoz agreed that Sandoz would not contest jurisdiction in this judicial district for this action.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count 1: Patent Infringement

7. Wyeth realleges paragraphs 1 through 6 above as if fully set forth herein.

8. On December 31, 2002, the United States Patent and Trademark Office duly and legally issued the '814 patent, entitled "Hormonal Contraceptive." A true and correct copy of the '814 patent is attached hereto as Exhibit A.

9. Wyeth is the assignee of the '814 patent, which discloses and claims, *inter alia*, methods for hormonal contraception.

10. Wyeth currently markets a prescription oral contraceptive product under the trademark LYBREL® pursuant to approved New Drug Application ("NDA") 21-864. LYBREL® is covered by the claims of the '814 patent. As the patent owner, Wyeth is authorized to enforce the '814 patent.

11. Upon information and belief, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 90-262 ("Sandoz ANDA") to the Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of LYBREL® before the expiration of the '814 patent.

12. On or about April 18, 2008, Plaintiff received a letter dated April 16, 2008 stating that Sandoz had filed the Sandoz ANDA seeking approval to manufacture, use and sell a generic version of LYBREL® before the expiration of the '814 patent. The letter purports to notify Wyeth that the Sandoz ANDA contains a certification pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that Sandoz's manufacture, use or sale of the Sandoz ANDA product will not infringe any claims of the '814 patent, that the '814 patent is invalid, and/or that the '814 patent is unenforceable.

13. Defendant is liable for infringement of the '814 patent under 35 U.S.C. §271(e)(2)(A) by virtue of its filing the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to expiration of the '814 patent.

14. Wyeth is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Sandoz ANDA be a date that is not a date earlier than the expiration of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth is or becomes entitled.

15. This case is an exceptional one, and Wyeth is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

16. Wyeth will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the '814 patent. Wyeth does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Wyeth seeks the following relief:

A. A judgment that Sandoz has infringed the '814 patent under 35 U.S.C. §271(e)(2)(A);

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sandoz ANDA, No. 90-262, be not earlier than the expiration date of the '814 patent, or any later expiration of exclusivity for the '814 patent to which Wyeth is or becomes entitled;

C. A permanent injunction restraining and enjoining Sandoz and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 90-262;

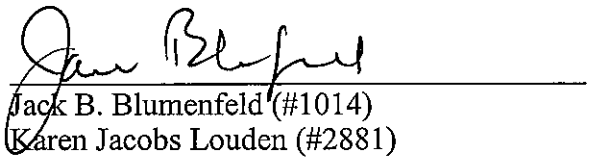
D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 90-262 would constitute infringement of the '814 patent, or inducing or contributing to such conduct, by Sandoz pursuant to 35 U.S.C. §271 (a), (b) and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. §285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Dated: May 28, 2008
2343115

EXHIBIT A

US006500814B1

(12) **United States Patent**
Hesch

(10) **Patent No.: US 6,500,814 B1**
(45) **Date of Patent: Dec. 31, 2002**

(54) **HORMONAL CONTRACEPTIVE**

(75) Inventor: **Rolf-Dieter Hesch**, Constance (DE)

(73) Assignee: **Wyeth Pharmaceuticals**, St. Davids, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/508,648**

(22) PCT Filed: **Sep. 3, 1998**

(86) PCT No.: **PCT/DE98/02636**

§ 371 (c)(1),
(2), (4) Date: **Jun. 5, 2000**

(87) PCT Pub. No.: **WO99/12531**

PCT Pub. Date: **Mar. 18, 1999**

(30) **Foreign Application Priority Data**

Sep. 11, 1997 (DE) 197 39 916

(51) **Int. Cl.**[7] **A61K 31/56**
(52) **U.S. Cl.** **514/170**; 514/841; 514/843
(58) **Field of Search** 514/170, 841, 514/843

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,855,305 A * 8/1989 Cohen 514/171
5,418,228 A * 5/1995 Bennink 514/182
5,898,032 A * 4/1999 Hodgen 517/178
RE36,247 E 7/1999 Plunkett et al.

FOREIGN PATENT DOCUMENTS

EP 0309263 * 3/1989
EP 0309263 B1 3/1989
EP 0 309 263 A1 3/1989
EP 0628312 B1 12/1994

OTHER PUBLICATIONS

Coutinho, E.M., et al. (1995) *Comparative Study on Intermittent Versus Continuous use of a Contraceptive Pill Administered by Vaginal Route.* Contraception 51(6):355–8.
Davies, Graham C., et al. (1992) *Ovarian Activity and Bleeding Patterns During Extended Continuous Use of a Combined Contraceptive Vaginal Ring.* Contraception 46(3):269–278.
Rizk, Diaa E.E., and Kumar, Rachana M., (1996) *Congential Afibrinogenemia: Treatment of excessive Menstrual Bleeding with Continuous Oral Contraceptive.* American J. Hematology 52(3):237–238.

* cited by examiner

Primary Examiner—Barbara P. Badio
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

The present invention relates to a hormonal contraceptive product having two hormonal components, an estrogen and a gestagen, and a process for the combined, continuous administration of the product of the invention.

3 Claims, No Drawings

HORMONAL CONTRACEPTIVE

This application is the U.S. National Phase under 35 U.S.C. §371 of International Application PCT/DE98/02636, filed Sep. 3, 1998, which claims priority of German application DE 19739916.9, filed Sep. 11, 1997.

The present invention relates to a hormonal contraceptive product with two hormonal components, the use thereof and a hormonal contraception process.

Since hormonal contraceptives became available in the 1960's, a number of hormonal components have been investigated with regards to their suitability in the most varied administration diagrams. A fundamental subdivision into combination and sequential products is possible.

For example, if the desired cycle time is 28 days, in the case of the known combination products administration takes place over 21 days in a constant or varying absolute and/or relative dosage of a combination of an estrogen product and a gestagen product, in which the estrogen product can e.g. be natural estrogen or synthetic ethinyl estradiol and the taking of the aforementioned 21 daily units is followed by a seven-day interval where there is a withdrawal bleeding simulating natural menstruation.

In the known sequential products, once again for a desired cycle time of 28 days, administration takes place for 7 days of a pure estrogen product and then for 15 days of a combination of an estrogen product and a gestagen product and here again there is then a taking-free period of e.g. 6 days when withdrawal bleeding occurs. It is admittedly already known to bridge the inherent taking intervals of combination and sequential products in the interest of greater taking security by administering within the days in question placebos. However, it has hitherto always been assumed that during the roughly one-week taking interval no hormones of the present type should be administered, in order to ensure a reliable withdrawal bleeding. Only in the case of substitution products in the menopause of older women have hormones been administered throughout the cycle, e.g. in the sequence 10 days estrogen product, 11 days combination of estrogen and gestagen product, 7 days estrogen product, 7 days estrogen product in a particularly low dosage, but said substitution products are unsuitable for ovulation inhibition.

The sequential products used in substitution therapy are in particular unsuitable for contraception because the natural estradiol does not prevent ovulation in the dosage administered and the phase in which gestagen is administered is too short, being only 11 days. However, in the case of the substitution products, the above-described sequential system guarantees a relatively good cycle control.

German patent 43 08 406 discloses a combination contraceptive product, which comprises one or more stages. At least one stage contains the combination of three components, namely a biogenous estrogen, a synthetic estrogen and a gestagen and the further stages in each case comprise a pharmaceutically unobjectionable placebo or a biogenous or synthetic gestagen, or a biogenous or synthetic estrogen, or a combination of two components, namely a biogenous estrogen, a synthetic estrogen and a gestagen or a combination of synthetic estrogen and a gestagen.

The description of the above document makes it clear that in the stage concept described therein there is typically a change of state over the period of time. Such a state change can take place in that the composition of the phases forming the stage is modified with respect to the components used and in that only the concentrations of the components used in the phases forming the stage undergo changes.

The problem of the invention is to provide a hormonal contraceptive product, which ensures high contraceptive safety or reliability and prevents inter-menstrual bleeding. There is also to be a further reduction in the side effects otherwise observed in hormonal contraceptive products.

According to the invention this problem is solved by a hormonal contraceptive product having two hormonal components, the agent comprising for continuous, combined administration a first hormonal component comprising at least one gestagen and a second hormonal component comprising at least one estrogen.

The problem is also solved by a hormonal contraception process, in which an a product, which comprises at least one first hormonal component, which comprises at least one gestagen, and a second hormonal component comprising at least one estrogen is continuously administered.

According to another aspect of the invention the product according to the invention is used for inhibiting ovulation.

According to a further aspect of the invention the product according to the invention is used for the treatment and/or prophylaxis of breast tumours.

According to another embodiment the invention proposes that gestagen as the first hormonal component is chosen from the group comprising progesterone, chlormadinone acetate, norethisterone acetate, cyproterone acetate, desogestrel, levenorgestrel, other natural and/or synthetic gestagens, anti-gestagens and hormonal analogs with gestagen or antigestagen action, as well as hormonal compounds which rapidly split off at least one gestagen following taking.

In the product according to the invention, the estrogen as the second hormonal component can be selected from the group comprising synthetic estrogens, biogenous estrogens, antiestrogens and hormonal analogs with estrogen or anti-estrogen action.

In a preferred embodiment the synthetic estrogen is selected from the group comprising ethinyl estradiol, mestranol and the like, as well as hormonal compounds rapidly splitting off at least one synthetic estrogen following taking.

In particularly preferred manner the synthetic estrogen is ethinyl estradiol.

In preferred embodiments the daily administered ethinyl estradiol quantity is 1 to 20 μg. In particularly preferred manner, the daily administered ethinyl estradiol quantity is 5 to 10 μg.

According to the invention the biogenous estrogen is selected from the group comprising estradiol, estriol, estrone, estrane, etc., as well as hormonal compounds rapidly splitting off at least one biogenous estrogen after taking.

According to an embodiment the estradiol comprises 17-α-estradiol and/or 17-β-estradiol.

According to another embodiment the daily administered biogenous estrogen quantity in the case of estradiol, particularly α and β-estradiol, is 0.1 to 2 mg and in the case of conjugate estrogens 0.05 to 0.5 mg.

In an embodiment the product according to the invention can be administered orally.

In an alternative embodiment the product according to the invention can be administered transdermally.

In a second alternative embodiment the product according to the invention can be administered intravaginally.

In a third alternative embodiment the product according to the invention can be in depot injection form.

In a fourth alternative embodiment the product according to the invention can be administered as a hormonal implant.

Finally, the daily units in each case comprising both hormonal components, are placed in spatially separated and individually removable manner in a packaging unit.

In an embodiment of the process according to the invention the first hormonal component can be administered in combination with the second hormonal component.

In another embodiment of the process according to the invention the product according to the invention is administered.

The invention is based on the surprising finding that as a result of the continuous, combined administration of a product comprising two hormonal components, namely a first hormonal component comprising at least one gestagen and a second hormonal component comprising at least one estrogen, a high contraceptive reliability can be achieved.

In accordance with modern opinion, estrogens are not understood to cover steroid molecules, which preferably evolve their action in that they in different ways exert a biological effect at different cell locations in different organs. Estrogens can act (1) on the cellular membrane, (2) intracellular, cytoplasmic proteins and (3) specific nuclear receptors. It has recently become known that besides the standard estrogen receptor type 1 there is a second estrogen receptor type 2, whose organ distribution is different from that of the estrogen receptor type 1.

Thus, the above definition also covers the compounds known as "designer hormones", which have the aforementioned characteristics.

Thus, biogenous estrogens are steroid molecules, which evolve an estrogen-like action on the membrane, cytoplasmic proteins and nuclear receptors for hydrophobic ring substances and consequently trigger biological effects corresponding to a hydrophobic steroid ring structure able to initiate an estrogen-like action in cells, organs and the complete organism.

The term biogenous estrogens also covers those estrogens which are produced by the human body and consequently include endogenic estrogens. The biogenous estrogens used in specific embodiments of the product according to the invention are typically those which are chemically synthesized. However, it is fundamentally also possible to use compounds isolated from an organism.

Biogenous estrogens also cover conjugate, biogenous estrogens such as e.g. estradiol valerate and estrone sulphate.

The term antiestrogens is here understood to mean hydrophobic ring structure substances and other substances able to specifically and selectively counteract the above-described estrogen action on cells, organs or the overall organism.

Continuous administration is here understood to mean an administration uninterrupted over the use period, in which there are no hormonal component taking-free intervals. This means that there is no interruption of the administration of the product by administering placebos in place of the hormonal product. Thus, over the administration period typically lasting several months to years there are no changes to the fundamental composition of the hormonal components. Instead over the entire administration period the hormonal components forming the hormonal product according to the invention are administered uninterrupted and unchanged with no modification to the concentration. However, it is conceivable for the concentration of estrogen, understood in the full breadth of the concept defined here, and gestagen, also understood in the full breadth of the term defined here, can be changed for older women compared with younger women. This can also take place in such a way that over the continuous administration period initially there is a start with a specific composition and this is then adapted over a period of weeks, months and years to the changed biological needs of the women through the administration of a subsequent product, but which also comprises a product according to the present invention.

As a result of the continuous administration of said hormonal components it is ensured that the natural hormonal processes taking place in the female organism do not interrupt the contraceptive security.

As a result of the estrogen component, respectively by specific action of hydrophobic ring substances with an estrogen-like action, there can be a suppression of gonadotropins. This is desirable. The resulting suppression of the ovarial function is compensated by an adequate substitution of estrogen action. This prevents the development of osteoporosis, the favourable vascular effects of estrogens are maintained and there is no unfavourable influence to the lipid metabolism. By interrupting the cycle-dependent instability in the hormone system, the premenstrual syndrome can be favourably influenced. In addition, the physiological equilibrium of the coagulation system is not disturbed, because the unstable equilibrium in which the coagulation system occurs is not activated and deactivated by the up and down of hormone fluctuations. Thus, the hormonal product according to the invention is particularly suitable for women aged more than 40, where the risk of circulatory disturbances is known to increase with increasing age. There is also a reduction in the thrombosis risk, which has of late acquired considerable significance in contraceptive therapy.

It has surprisingly also been found that on administering the product according to the invention there is a reliable continuous suppression of the menstrual cycle and menstruation in the case of a very low dosage. Without wishing to be bound by this explanation, the combination of the two indicated hormonal components and in particular the low estrogen dosage would appear to be suitable for eliminating the otherwise conventional side effects of ethinyl estradiol and to drop below the administrations of more than 15 μg of ethinyl estradiol otherwise considered typically necessary in prior art contraceptives.

The low dosage of the two hormonal components and in particular the estrogen component is made possible by the additive action of the two hormonal components, without there being any limitation to the action of the product according to the invention with respect to its contraceptive and ovulation-inhibition properties.

The ovulation inhibition and menstrual cycle suppression reliably ensured by the product according to the invention is of great significance for certain patients, such as e.g. for top sports women, dancers and business women, who wish to exclude any reduction in their physical, intellectual and emotional efficiency as a result of the menstrual cycle. As a result of the combined, continuous administration of the two hormonal components of the product according to the invention it is possible to administer the same either orally, transdermally, intravaginally, by depot injections or hormone implants. Here again the advantages observed for the particular administration forms are obtained.

Possible oral administration forms are all the forms known from the prior art such as e.g. tablets, dragees, pills or capsules, which are produced using conventional adjuvants and carrier substances.

In the transdermal administration of the product according to the invention the two hormonal components forming the product can e.g. be applied to a plaster or also can be applied by transdermal, therapeutic systems and are consequently supplied to the organism. For example an already prepared combination of the two hormonal components or the latter individually can be introduced into such a system, which is based on ionotherapy or diffusion or optionally a combination of these effects.

In the case of oral administration it has proved appropriate to place the daily units, which in case comprise a combination of the two hormonal components, in a spatially separated and individually removable manner in a packaging unit, so that it is easy to check whether the typically daily taken, oral administration form has in fact been taken. It is important to ensure that there are no taking-free days. Depot injections can be administered at 1 to 6 months or longer intervals. Hormonal implants contain both hormonal components and deliver the same over a period of preferably 3 to 6 months.

When using the product according to the invention it has surprisingly been found that the treatment and/or prophylaxis of breast tumours is possible. The latest breast cancer risk research has revealed that mutations, which can be hereditary or acquired, occur in certain risk genes. Modern cancer therapy assumes that a cancerogenic mutation is present on one of the two allels of a gene which is initially controlled by the other, healthy allel. If a further mutation occurs in a specific organ cell on the second allel, then uncontrolled, malignant growth can occur.

Mutations on the second allel particularly frequently occur in given phases of the cell cycle, namely in the G1 phase. Every four weeks the menstrual cycle drives the breast cell in a cell cycle, "opens" the genome for mutations, which are either repaired or apoptotically "removed". Under the conditions of the conventional combined or sequential contraception treatment a women can have 500 to 700 cycles over her life span, whereas under natural conditions a women has a maximum of 20 to 30 cycles. Thus, in an unusually frequently number of cell cycles over in each case 8 days a considerable mutation risk is introduced into the stimulated breast tissue. If the menstrual cycle is suppressed, as is possible with the product according to the invention, the breast cells are brought into a "rest phase" and it is scientifically ensured that in the rest phase less cancerogenic mutations are introduced into a tissue than in a stimulated tissue. This reduces by a multiple mutagenesis, i.e. the breast cancer risk.

The aforementioned use of the product according to the invention for the treatment and/or prophylaxis of breast cancers is in particular associated with special advantages if the users of the product are high-risk subjects, such as e.g. those with a high family breast cancer risk.

The quantity of administered gestagens and estrogens substantially corresponds to the quantity of comparable prior art products. The examples provide further information concerning the quantities to be administered daily of the different compounds forming the first and/or second hormonal components.

The invention is explained in greater detail hereinafter relative to examples revealing further features, advantages and embodiments of the present invention.

EXAMPLE 1

For contraceptive treatment use was made of a product which per daily unit in table form contained 5 μg of ethinyl estradiol and 2 mg of norethisterone acetate. It is noteworthy that norethisterone acetate can be used in a concentration range of 0.5 to 5 mg. The product was administered for 9 months and revealed a very good contraceptive reliability whilst completely suppressing the menstrual cycle with no side effects. Within the framework of the present investigation it was ensured that the test persons took the product daily, i.e. without any taking interval, over the entire aforementioned time period.

EXAMPLE 2

For contraceptive treatment use was made of a product which per daily unit in table form contains 0.5 mg of estriol and 2 mg of chlormadinone acetate. It is noteworthy that estriol can be used in a concentration range of 0.5 to 3 mg and chlormadinone acetate in a concentration range of 0.75 to 5 mg. The product was administered for 12 months without any taking interval. The mode of action corresponded to that of example 1.

EXAMPLE 3

For contraceptive treatment use was made of a product which in each daily unit in tablet form contained 0.5 mg of estradiol valerate and 2 mg of lynestrenol. It is noteworthy that estradiol valerate can be used in a concentration range of 0.5 to 5 mg and lynestrenol in a concentration range of 0.5 to 4.5 mg. The product was administered for 12 months without any taking interval. The mode of action corresponded to that of example 1.

EXAMPLE 4

For contraceptive treatment use was made of a product containing per daily unit in tablet form 7.5 μg of ethinyl estradiol and 75 ug of desogestrel. It is noteworthy that desogestrel can be used in a concentration range of 50 to 200 μg. The product was administered for 12 months without any taking interval. The mode of action corresponded to that of example 1.

EXAMPLE 5

For contraceptive treatment use was made of a product containing per daily unit in tablet form 20 mg of tamoxifen and 2 mg of lutenyl. It is noteworthy that tamoxifen can be used in a concentration range of 10 to 50 mg and lutenyl in a concentration range of 1 to 5 mg. This product is preferably suitable for contraception in women with a family breast cancer risk. The product was administered for 12 months without any taking interval and the mode of action corresponded to that of example 1.

EXAMPLE 6

For contraceptive treatment use was made of a product containing per daily unit in tablet form 50 mg of raloxifen and 2.5 mg of medroxyprogesterone acetate (MPA). It is noteworthy that raloxifen can be used in a concentration range of 30 to 100 mg and medroxyprogesterone acetate in a concentration range of 2 to 10 mg. This combination is preferably suitable for women with a family breast cancer risk and young women who have suffered breast cancer. The product was administered for 12 months without any taking interval and the mode of action corresponded to that of example 1.

EXAMPLE 7

For contraceptive treatment use was made of an agent containing per daily unit in tablet form 10 μg of ethinyl estradiol and tibolone in a daily concentration of 2 mg. It is noteworthy that tibolone can be used with a concentration of 1 to 10 mg. The product was administered without any taking interval for 12 months and the mode of action corresponded to that of example 1.

EXAMPLE 8

For contraceptive treatment use was made of a product containing per daily unit in tablet form 10 μg of ethinyl estradiol and as the antiestrogen substance Ro486 in a concentration of 2.5 mg. It is noteworthy that R0486 can be

used in a concentration range of 1 to 7.5 mg. The product was administered without any taking interval over a period of 12 months and the mode of action corresponded to that of example 1.

The features of the invention described in the description and claims can be essential individually and in random combination for the implementation of the different embodiments of the invention.

What is claimed is:

1. A method for hormonal contraception, comprising:

administering orally, transdermally or via depot to a mammal in need thereof, for a continuous and uninterrupted administration period of greater than 110 days, a contraceptive product comprising:

a gestagen selected from the group consisting of progesterone, chlormadinone acetate, norethisterone acetate, cyprotherone acetate, desogestrel, and levonorgestrel; and

an estrogen selected from the group consisting of ethinyl estradiol, mestranol, estradiol, estriol, estrone, and estrane;

wherein said gestagen and said estrogen are present in said contraceptive product at unchanged dosages throughout the administration period, and when said estrogen is ethinyl estradiol, the dosage of ethinyl estradiol is not greater than 20 μg per day.

2. The method of hormonal contraception of claim 1 wherein the dosage of ethinyl estradiol is between 1 and 20 μg per day.

3. A method for continuous suppression of the menstrual cycle, comprising:

administering orally, transdermally or via depot to a mammal in need thereof, for a continuous and uninterrupted administration period of greater than 110 days, a contraceptive product comprising:

a gestagen selected from the group consisting of progesterone, chlormadinone acetate, norethisterone acetate, cyprotherone acetate, desogestrel, and levonorgestrel; and

an estrogen selected from the group consisting of ethinyl estradiol, mestranol, estradiol, estriol, estrone, and estrane;

wherein said gestagen and said estrogen are present in said contraceptive product at unchanged dosages throughout the administration period, and wherein the dosage of ethinyl estradiol is not greater than 20 μg per day, such that the menstrual cycle is continuously suppressed throughout the administration period.

* * * * *

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Wyeth

DEFENDANTS
Sandoz, Inc.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
35 U.S.C. § 271

Brief description of cause:
patent infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Farnan DOCKET NUMBER 08-145

DATE May 28, 2008

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.